Exhibit 31

FTC Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics Workshop
November 8, 2017
Segment 3: Panel 2
Transcript

DAVID SCHMIDT: Good morning. I'm Dave Schmidt. I'm an assistant director in the Bureau of Economics, here at the FTC. I'd like to welcome everybody here to this panel, those here in person plus the people watching on the internet. I'd especially like to acknowledge Congressman Buddy Carter of Georgia. Welcome, Congressman Carter. Just a little time bookkeeping here. We started a little late because of a fire alarm in the building or a security thing. We're going to try to get back on time. We're going to end this panel at 1 o'clock, at which point we'll break for an hour for lunch, and would like to get back on schedule, then, following lunch. So we'll start the third panel at 2:00 p.m.

So as we heard in the previous session, there are many entities that get involved in pharmaceutical markets between the manufacturer who makes the drug and the patients who take the drugs. These next two sessions are going to focus on the roles of two types of intermediaries in the pharmaceutical supply chain, pharmacy benefit managers, which will be this panel, and then group purchasing organizations. Just to give you a little background on pharmacy benefit managers, or PBMs, as is usually the case in the healthcare sector, the terms of trade for most prescription drug purchases are heavily influenced by insurance coverage. For instance, IMS Health estimates that a little more than half of all prescriptions filled at retail pharmacies are filled under a pharmacy benefit plan managed by a commercial third-party payer, for instance, the health insurance that someone might receive from their employer or from their union. And another quarter of all prescriptions are filled under Medicare Part D plans, which operate very similarly in many important respects. The companies who manage or administer these pharmacy benefit plans are naturally pharmacy benefit managers.

From the perspective of those of us who get our prescriptions filled, the main role that the PBM plays is to help us find a place to get the prescription filled, and to work out all the payments to the pharmacy and from our employer, and work out all the payment schemes. However, the primary client of the PBM is not actually us, the end-consumer. It's the plan sponsor, our employer, or union, or whoever is providing the benefit. In conjunction with that plan sponsor, the PBM works out to design the specifics of the plan, decide which drugs will be covered. They might negotiate rebates or discounts with drug manufacturers. They sign contracts with pharmacies to have the prescriptions filled when we walk in with our prescription. PBMs also, as we heard in the first session, typically own their own mail order pharmacy. And that was the subject of a 2005 FTC study. Additionally PBMs, many of them, own their own specialty pharmacies that dispense difficult to handle or very expensive drugs.

In order to provide all these different services, PBMs have to engage many of the other participants in the drug supply chain. This panel will explore the relationships the PBMs have with those other entities in order to understand what effect they have on drug prices, quality of coverage, and consumer access. Given the complexity of this topic, I'm very happy to have a very esteemed panel here to help us sort through these issues. In the interest of saving scarce

So in closing the PBM marketplace is highly competitive. It's driven by the various and ever-evolving demands of the marketplace. It's a disruptive marketplace. When I first got here at PCMA, I'm not sure that even two or three of the companies that were in the industry then, 15 years ago, are even there now. It is constantly changing, and that's a good thing. Marketplace competition gives payers a wide variety of PBM choices, so that each payer can offer the kind of prescription drug coverage that is best for them, that is most cost effective for them, and best for their enrollees. And that is the bottom line. If the marketplace, if big payers find value with PBMs, great. They know what they're doing. They should get it. If they don't, they can go another way. But the reality is, regardless of all the input costs or all the discussions of middlemen, supply chain, and so forth, the reality is PBMs offer tremendous value, or else the smartest, largest, best purchasers in America wouldn't use us as they do today. So thank you very much. [APPLAUSE]

JENNIFER BRYANT: Hello, I'm Jenny Bryant from the Pharmaceutical Manufacturers. I want to just, maybe, jump straight to the bottom line because I think there are some things that, maybe, we all agree on. And that is that this is really all about competition, and that the key here, when we're talking about rebates, which I think we're going to be doing most of the day today, is to make sure that those rebates and negotiated savings are benefiting patients. And the health care system, more broadly, that they're working in the service of getting us better outcomes at lower prices. And I would argue that the degree to which the market has been working is, in part, the result of the success of intermediaries. So it's not about whether we need intermediaries. It's about the terms of competition and making sure that the market is working well for everyone. And I would argue that the market can, in fact, work better than it is today, and that we can bring negotiated savings to patients better than we're doing today.

Since we've talked about drug costs several times already, I won't dwell on this. But I would argue that, in fact, the trends in drug costs growth, despite what you read in the paper, are much more modest than are frequently claimed. I'm showing you here the year over year trend for the largest pharmacy benefit managers, which as you've now heard, control a large share of the market. We're showing for 2016 low digit growth in 2016, right? Much lower than in 2015. And one of the largest PBMs, Prime Therapeutics, has just released data for the first half of 2017 showing growth under 1%. These are not the numbers you, generally, are hearing when you, generally, are reading about drug costs and drug prices you're reading about, list price growth, which we can talk about. But these numbers, I would argue, do not represent an unsustainable path, in terms of drug costs growth. And in fact, these numbers take into account the fact that we've been bringing dozens of new medicines to the market every year, fundamentally transforming the way that care is delivered.

When you hear about drug costs, most of the concern has been about what we would call list price growth. And here I'm showing you data from IMS Institute. The top line shows the list price growth and the bottom line shows the actual final price to payers after rebates and discounts are removed. So here we're showing price growth in 2016 of 3.5%, which is obviously very different from the top line growth. So why does this matter? It matters in many, many markets because the fact is that patients are now exposed, increasingly, to those undiscounted top line prices. And they're not small differences. If you take the example of the insulin market, for example, which is frequently the target of criticism for list price growth, the publicly reported

average rebates in that market now are approaching 70%. And so, for patients, that could make a very large difference

I'd also say that as we just looked at this for a moment, people are asking why do we see this big gap between the gross price and the net price. What caused that? I'm sure people will have answers for that today as we talk more. And what are the consequences, besides the consequences for patients in terms of their cost sharing, is also potentially leading to changes in the way that formularies are created and changing the incentives because so much more of the money now is tied up in these rebates and discounts. Of course, as I think Dr. Sood just alluded to, many of the fees and the revenue streams for the pharmacy benefit managers are tied to those list prices. That's largely passed through to employers, but we'll come to that in a moment.

Again, I just want to make clear that the patients are the reasons that we should be concerned about the system here. And if it's working for patients, then it will work for all of us. So we did some work recently to understand what share of patient cost sharing is tied to the list price. And that showed that more than half of the spending, or about half of the spending, that patients pay out of pocket is in fact tied to this list price. That's because patients have deductibles, and patients pay co-insurance which is a percentage of that undiscounted price. That's one in five brand prescriptions. So, of course, the majority of prescriptions are still paid with co-pays. We're not talking about those prescriptions, but for patients who are sick and who are taking medicines, and particularly medicines that carry large rebates, they are not getting the benefit of these discounts which, as I said, can be substantial and can run into the hundreds , potentially even the thousands of dollars for some patients.

I think earlier Dr. Schondelmeyer made the case that it's the premium that matters, not the cost sharing. Well, of course premium matters for everyone. It matters, especially for healthy patients. But if you're a sick patient, the cost sharing really does matter. And there are very few options, once a drug has been on the market, for a manufacturer to address challenges of access for patients, other than to offer a cost sharing coupon or co-pay assistance. If you were to lower the price to the health plan through a rebate, as we've just now see, though that net price isn't what determines the patient's cost. So we have a situation in which patients are increasingly, because of high deductibles, which are much, much more common, being exposed to this list price. And there aren't too many ways to get those savings to them, other than changing this construct or offering cost sharing assistance.

So as you've heard, the pharmacy benefit manager market is very concentrated. We've talked less about the tools that insurers and PBMs have to control access. I would argue that, in fact, PBMs and insurers can pretty much determine if, when, and how a medicine is used. And they do that very effectively. And that has been the engine for why costs have been kept in check over a long period of time. So I'm not arguing that rebates are something that needs to go. They've been used effectively and they do allow for varying levels of discounts, which can be helpful in keeping the average level of price down, but I do think it's important to recognize that there is quite a lot of concentrated power here and you have three, essentially, large PBMs controlling almost 70% of the market. This is up from the top three controlling less than half of the market back in 2011, and that's a very substantial change.

that case, you're going to be making x amount of dollars. I want to drive a harder bargain in my contract with you." But right now, they have are completely in the dark about that.

So some of the different revenue streams, other than rebates, that I want to cover a little bit. Obviously, we have rebate agreements, and PBMs claim they passed along about 90% of the rebates. However, there are some caveats with that. Many PBM contracts allow PBMs to essentially relabel rebates. So these rebate amounts are reclassified as formulary management or data management fees. So even if they have a contract in which the PBM has to return all of the rebates, these amounts would not be covered under that Spread profits. This is specifically at the pharmacy level. So the amount paid to the pharmacy is lower than the amount charged to the plan or the employer on every single drug. And this is not necessarily disclosed to the plan. And keep in mind that's every single prescription that's run through. They make a profit on that. PBM-owned mail order, and specialty pharmacies, and then, also, data. They sell the data of all of all the beneficiary data, which can be significant.

So PBM influence in retail pharmacy-- So as I mentioned, they contract with retail pharmacies to form these pharmacy networks. At the same time, these network pharmacies compete with the PBM's pharmacies. Another example of how this is also convoluted. With the CVS Caremark, you have a combination of one of the largest PBMs with one of the largest retail pharmacy chains. PBM side of that business has direct access to the sensitive records of pharmacies that are in direct competition with the retail chain. And then also, PBMs determine pharmacy reimbursement amounts for virtually all prescription drugs that go through insurance.

PBMs also audit retail pharmacies. They have access to very detailed financial information and drug purchasing records. They can access all the invoices. PBMs also wields absolute control over pharmacy reimbursement for all the generics. PBMs have what are known as proprietary MAC lists. This is key. Brand name drugs have public benchmarks. Anyone can access what those are. MAC lists, these do not exist. That's totally considered proprietary on the part of the PBM.

I do want to touch a little bit on MAC pricing. So maximum allowable costs. These were created by PBMs to determine the maximum amount that they're going to reimburse the pharmacy for a generic product. And the reasoning behind this, originally, was to make sure that pharmacies were purchasing at the lowest prices, which is a valid goal. However, I would say in practice this really does not work because there is absolutely no transparency. Pharmacies have no idea where to obtain some of these prices and the PBM's claim that the methodology as to where they got these from are completely proprietary. This results in a lot of pharmacies being underwater on claims. They're losing money by filling prescriptions. Again, MAC lists. They use one MAC list to reimburse the pharmacy, which is aggressively low, and one to charge the plan sponsor, which is high. Again, that's the spread pricing. Again, pharmacies sign these contracts with PBMs having absolutely no insight into what the MAC list looks like. When a pharmacy gets a contract, it says you'll be reimbursed for all generics based on MAC. That's it.

I would be remiss if I did not cover the next topic, as this is the number one topic for my members right now. Pharmacy DIR fees. DIR was really a Medicare Part D concept. It's stands for direct and indirect remuneration. It was really designed to account for manufacture rebates